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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,427	12/31/2003	Frank Fago	L-F/217/273	1785

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EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
05/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,427	FAGO ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment filed on 3/12/08 has been entered.

Claims 9-24 are present for examination.

Claims 1-8 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 18 is misdescriptive. According to the Specification and the Fig. 7, the step of "determining if expulsion of at least some of the medical fluid from the syringe has occurred" is not disclosed. According to the Spec and Fig. 7, the fluid is drawn in at a first fill rate, the ram expels contrast fluid from the syringe, at this point, the air is pushed out, and the syringe is then filled at a second fill rate. At no point in the Specification or in Figure 7 does the system make a determination as to whether or not the expulsion has occurred.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation “filling the syringe at a first fill rate wherein aeration of the contrast media is prevented” of claim 9 is vague. Does Applicant mean that “filling the syringe with the rate to avoid aerating the contrast media?

Additionally, the limitation: "said first fill rate being faster than a second fill rate that is a maximum fill rate if air **is not previously expelled** from the fill tube” of claim 9 is vague and unclear. Does applicant mean that the "the first fill rate determined in step 910, (which is filling the syringe stage) is faster than the second rate that is a maximum fill rate; wherein the second fill rate determined if the air does not expel from the tube? In other words, the second fill rate includes the maximum fill rate plus the some air is in the fill tube as in step 908.

Also, the recitation “a second fill rate is a maximum fill rate” is vague and unclear. The “maximum fill rate” can be understood that “fastest or highest fill rate”. At this point, it is contradict with first fill rate where is faster than the second fill rate.

For examining purpose, Examiner interprets the second fill rate includes the maximum fill rate with some air is in the fill tube.

Similarly, in claim 18, the limitation “wherein the filling occurs at a second fill rate that is faster than the first fill rate if the determining results in a determination that at least some of the medical fluid has been expelled from the syringe” is unclear and confusing. Again, does applicant mean that “the first rate determined in step 906, (which is pull small amount of contrast into syringe); and the second fill rate step determined in step 910, (which is filling the syringe stage after the step of the air is pushed out)?”

Applicant wrote that: “As agreed during the interview, Applicants have amended each of independent claims 9, 12 and 18 to recite a first “fill” rate and a second “fill" rate so it is abundantly clear…” (see Remark on pgs 8-9 mailed on 3/12/08).

In response, during the interview, Examiner suggested Applicant should amend claim more clearly to over come 112, second paragraph rejection. Examiner did not give any input nor agree to the current claim language. The claim languages are still unclear after Applicant amended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 5,573,515).

Regarding claims 9, as best as understood, Wilson discloses a method comprising: the step of expelling substantially all air from the fill tube (any air ejected, coll. 2, line 11), thereafter, filling the syringe at the first rate. It is noted that user may adjust rate, furthermore there is a flow rate display, 264, and evidence that the flow rate is changed at col. 12, lines 20-22; wherein aeration of the contrast media is prevented (contrast fill operation repeated, col. 5, line 63); the first fill rate being faster than a second fill rate (flow rate changeable, col. 2, lines 15-20, col. 4, lines 15-25; or col. 11, line 25 - col. 12 line 22) that is a maximum fill rate if air is not previously expelled from the fill tube.

Regarding claims 10-11, the step of expelling includes drawing a first amount of contrast media into the syringe (col. 6, lines 1-2) and expelling the first amount of the syringe and fill tube; or wherein the step of expelling and/or filling are performed by the contrast media injector automatically under the control circuitry of the injector (col. 6, line 30).

Regarding claims 12-17, similarly to rejection of claims 9-11 above, Wilson further discloses a method for changing contrast media containers during a syringe filling sequence, comprising the steps of pausing the syringe filling sequence of a syringe when a first contrast container is substantially emptied (col. 9, line 63+); replacing the first contrast container with a second contrast container; expelling

substantially all air from a fill tube coupled between the syringe and second contrast container (col. 10, line 13); and thereafter, resuming filling the syringe from the second contrast container at a first rate wherein aeration of the contrast media is prevented (col. 5, line 63).

Regarding claims 18, 21-24, as best as understood, Wilson discloses a method comprising: drawing medical fluid into a syringe of a contrast media injector system at a first rate; expelling substantially all air from the fill tube (any air ejected, col. 2, line 11). It is noted that when expelling air out from the tube or syringe, one skill in the art to recognize that at least some of the medical fluid from the syringe has occurred to make sure all air out. Thereafter, the full filling occurs at a second rate (user will meter the amount and rate of contrast material injected, col. 5, lines 43-50 and col. 12, lines 20-22). Because the air being light than the contrast material, gathers near the top of syringe body. Therefore, the first rate of the step of expelling all air from the fill tube/syringe, including some medical fluid expelled from syringe must be slowly occur. For example, if the user applies big force, the plunger moves fast, (which is the first rate increase also), there will be air and all medical fluid/contrast material move out the syringe/fill tube which is the user does not want. Hence, the second rate is faster than the first rate. Wilson further discloses that flow rate changeable (col. 11, lines 25-30 or col. 12, lines 20-22). Therefore, one skill in the art would recognize that the second rate can be faster than first rate if the user wants to change the flow rate.

Regarding claim 19, the first rate is a rate sufficient to avoid aeration of the medical fluid (contrast fill operation repeated, col. 5, line 63+)

Regarding claim 20, Wilson discloses the claimed invention except for the step of drawing at least 20ml of the medical fluid in to the syringe. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to drawing 20ml of fluid, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Response to Arguments

Applicant's arguments filed 03/12/08 have been fully considered but they are not persuasive.

Please see the rejection of claims 9-24 above for more details. Beside that, Examiner has clarified more specifically the points which are pertinent to applicant's current claims. Although Examiner understands Applicant's arguments regarding the differences between the prior art and the instant applicant, Examiner feels that these differences are not distinguish over the prior art, and that the current claims read on a conventional fill sequence. Examiner specifically points out in col. 5 where the "user will meter the amount and rate of contrast material injected…" (line 44+ and at line 61, "the contrast fill operation is performed during initial set up of system and maybe be repeated during operation of system whenever syringe body is running low on radiographic contrast material." (emphasis added). This indicates that before syringe is completely emptied, it is expelled of air and refilled, and this process may happened over again, and that the user can alter the rate and amount for the safety of the patient.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
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